

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of Health Policy

3 (Amendment)

4 900 KAR 6:075. Certificate of Need nonsubstantive review.

5 RELATES TO: KRS 216B.010, 216B.015, 216B.090 [~~216B.095~~], 216B.455,
6 216B.990

7 STATUTORY AUTHORITY: KRS [~~194A.030, 194A.050,~~] 216B.040(2)(a)1,
8 216B.095

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.040(2)(a)1 requires the
10 Cabinet for Health and Family Services to administer Kentucky's Certificate of Need
11 Program and to promulgate administrative regulations as necessary for the program.
12 KRS 216B.095 authorizes the review of certificate of need applications that are granted
13 nonsubstantive status. This administrative regulation establishes the requirements
14 necessary for consideration for nonsubstantive review of applications for the orderly
15 administration of the Certificate of Need Program.

16 Section 1. Definitions. (1) "Ambulatory surgical center" is defined by KRS
17 216B.015(4).

18 (2) "Cabinet" is defined by KRS 216B.015(6).

19 (3) "Certificate of Need Newsletter" means the monthly newsletter that is published
20 by the cabinet regarding certificate of need matters and is available on the Certificate of
21 Need Web site at <http://chfs.ky.gov/ohp/con>.

1 (4) "Days" means calendar days, unless otherwise specified.

2 (5) "Formal review" means the review of an application for certificate of need which
3 is reviewed within ninety (90) days from the commencement of the review as provided
4 by KRS 216B.062(1) and which is reviewed for compliance with the review criteria set
5 forth at KRS 216B.040 and 900 KAR 6:070.

6 (6) "Nonsubstantive review" is defined by KRS 216B.015(18).

7 (7) "Public information channels" means the Office of Communication and
8 Administrative Review in the Cabinet for Health and Family Services.

9 (8) "Public notice" means notice given through:

10 (a) Public information channels; or

11 (b) The cabinet's Certificate of Need Newsletter.

12 ~~[(9) "Therapeutic cardiac catheterization outcomes" means in hospital mortality~~
13 ~~rates, door to balloon time, door to balloon time less than or equal to ninety (90)~~
14 ~~minutes, Percutaneous Coronary Intervention (PCI) related cardiac arrests, and~~
15 ~~emergency open heart surgeries performed as a result of the PCI.]~~

16 Section 2. Nonsubstantive Review. (1) The cabinet shall grant nonsubstantive
17 review status to an application to change the location of a proposed health facility or to
18 relocate a licensed health facility only if:

19 (a) There is no substantial change in health services or bed capacity; and

20 (b)1. The change of location or relocation is within the same county; or

21 2. The change of location is for a psychiatric residential treatment facility.

22 (2) The cabinet shall grant nonsubstantive review status to an application that
23 proposes to establish an ambulatory surgical center pursuant to the conditions specified

1 in KRS 216B.095(7).

2 (3) In addition to the projects specified in KRS 216B.095(3)(a) through (e), pursuant
3 to KRS 216B.095(f), the Office of Health Policy shall grant nonsubstantive review status
4 to an application for which a certificate of need is required if:

5 (a) The proposal involves the establishment or expansion of a health facility or
6 health service for which there is not a component in the State Health Plan;

7 (b) ~~The proposal involves an application from a hospital to reestablish the number~~
8 ~~of acute care beds that it converted to nursing facility beds pursuant to KRS~~
9 ~~216B.020(4), if the number of nursing facility beds so converted are delicensed;~~

10 (c) The proposal involves an application to relocate or transfer certificate of need
11 approved acute care beds or licensed acute care beds, not including neonatal Level III
12 or IV beds, from one (1) existing licensed hospital to another existing licensed hospital
13 within the same area development district and the requirements established in this
14 paragraph are met.

15 1.a. There shall not be an increase in the total number of licensed acute care beds
16 in that area development district; and

17 b. The hospital from which the licensed beds are relocated delicensures those beds.

18 2. If neonatal Level II beds are relocated or transferred pursuant to this paragraph:

19 a. The receiving hospital shall have an existing licensed Level II, ~~or~~ Level III, or IV
20 neonatal unit;

21 b. A minimum of four (4) beds shall be relocated; and

22 c. The relocation shall not leave the transferring hospital with less than four (4)
23 neonatal Level II beds unless the relocated beds represent all of its neonatal Level II

1 beds;

2 ~~(c)~~~~(d)~~ The proposal involves an application by an existing licensed hospital to:

3 1. Convert licensed psychiatric or chemical dependency beds to acute care beds,
4 not including special purpose acute care beds such as neonatal Level II beds, ~~or~~
5 ~~neonatal~~ Level III beds, or Level IV beds;

6 2. Convert and implement the beds on-site at the hospital's existing licensed facility;
7 and

8 3. Delicense the same number of psychiatric or chemical dependency beds that are
9 converted;

10 ~~(d)~~~~(e)~~ The proposal involves an application by an existing licensed hospital
11 providing inpatient psychiatric treatment to:

12 1. Convert psychiatric beds licensed for use with geriatric patients to acute care
13 beds, not including special purpose acute care beds such as neonatal Level II beds, ~~or~~
14 ~~neonatal~~ Level III beds, or Level IV beds;

15 2. Convert and implement the beds on-site at the existing licensed hospital; and

16 3. Delicense the same number of converted beds;

17 ~~[(f) The proposal involves an application by a psychiatric hospital to convert licensed~~
18 ~~geriatric, adult, adolescent, or child psychiatric beds to psychiatric beds and the~~
19 ~~requirements established in this paragraph are met.~~

20 ~~— 1. The psychiatric hospital is located within twenty (20) miles of a United States~~
21 ~~military base;~~

22 ~~— 2. The psychiatric hospital provides inpatient behavioral health services to active~~
23 ~~duty military personnel, families of active duty military personnel, and veterans;~~

~~3. The psychiatric hospital shall convert and implement the beds on-site at the existing licensed hospital; and~~

~~4. The psychiatric hospital shall delicense the same number of converted beds.~~

~~(g) The proposal involves an application to transfer or relocate existing certificate of need approved nursing facility beds between certificate of need approved nursing facilities or from a certificate of need approved nursing facility to a proposed nursing facility and the requirements established in this paragraph are met.~~

~~1. The selling or transferring facility has a certificate of need nursing facility bed inventory of at least 250 beds;~~

~~2. The transfer or relocation takes place within the same Area Development District;~~

~~3. The application includes:~~

~~a. A properly completed OHP Form 9, Notice of Intent to Acquire a Health Facility or Health Service, incorporated by reference in 900 KAR 6:055; and~~

~~b. Evidence of the selling or transferring entity's binding commitment to sell or transfer upon approval of the application; and~~

~~4. A certificate of need approved nursing facility shall not sell or transfer more than fifty (50) percent of its certificate of need approved nursing facility beds;~~

~~(h) The proposal involves an application to establish a therapeutic cardiac catheterization program and the requirements established in this paragraph are met.~~

~~1. The applicant is an acute care hospital which was previously granted a certificate of need to participate in a primary angioplasty pilot project and was evaluated after the first two (2) years of operation by an independent consultant who determined the hospital successfully demonstrated good therapeutic cardiac catheterization outcomes.~~

- 1 ~~—2. The applicant shall document that the nursing and technical catheterization~~
2 ~~laboratory staff are experienced and participate in a continuous call schedule.~~
3 ~~balloon pump support.~~
- 4 ~~—3. The applicant shall document that the catheterization laboratory shall be~~
5 ~~equipped with optimal imaging systems, resuscitative equipment, and intra-aortic~~
- 6 ~~—4. The applicant shall document that the cardiac care unit nurses shall be proficient~~
7 ~~in hemodynamic monitoring and intra-aortic balloon pump management.~~
- 8 ~~—5. The applicant shall document formalized written protocols in place for immediate~~
9 ~~and efficient transfer of patients to an existing licensed cardiac surgical facility.~~
- 10 ~~—6. The applicant shall utilize a Digital Imaging and Communications in Medicine~~
11 ~~(DICOM) standard image transfer system between the hospital and the backup surgical~~
12 ~~facility.~~
- 13 ~~—7. The applicant shall employ an interventional program director who has performed~~
14 ~~more than 500 primary PCI procedures and who is board certified by the American~~
15 ~~Board of Internal Medicine in interventional cardiology.~~
- 16 ~~—8. The applicant shall document that each cardiologist performing the therapeutic~~
17 ~~catheterizations shall perform at least seventy-five (75) PCIs per year.~~
- 18 ~~—9. The applicant shall document the ability to perform at least 200 interventions per~~
19 ~~year, with an ideal minimum of 400 interventions per year by the end of the second year~~
20 ~~of operation.~~
- 21 ~~—10. The applicant shall participate in the American College of Cardiology National~~
22 ~~Cardiovascular Data Registry quality measurement program.~~
- 23 ~~—11. The applicant shall report therapeutic cardiac catheterization data annually to~~

1 the Cabinet for Health and Family Services.

2 ~~— 12. The application shall document the applicant's ability to produce therapeutic~~
3 ~~cardiac catheterization outcomes which are within two (2) standard deviations of the~~
4 ~~national means for the first two (2) consecutive years;~~

5 ~~— (i) The proposal involves an application to transfer or relocate existing certificate of~~
6 ~~need approved nursing facility beds from one (1) long-term care facility to another long-~~
7 ~~term care facility and the requirements established in this paragraph are met.~~

8 ~~— 1. The selling or transferring facility fails to meet regulations promulgated by the~~
9 ~~Centers for Medicare and Medicaid Services at 42 C.F.R. 483.70(a)(8) requiring nursing~~
10 ~~facilities to install sprinkler systems throughout their buildings;~~

11 ~~— 2. The selling or transferring facility may sell or transfer portions of its total bed~~
12 ~~component to one (1) or more existing nursing facility;~~

13 ~~— 3. The facility acquiring the beds shall be located in a county contiguous to that of~~
14 ~~the selling or transferring facility;~~

15 ~~— 4. The selling or transferring facility shall be licensed only for nursing facility beds at~~
16 ~~the time of transfer or application to transfer and shall not sell or transfer more than~~
17 ~~thirty (30) of its licensed nursing facility beds to an individual facility; and~~

18 ~~— 5. The application shall include a properly completed OHP Form 9, Notice of Intent~~
19 ~~to Acquire a Health Facility or Health Service, incorporated by reference in 900 KAR~~
20 ~~6:055;]~~

21 (e)(ii) The proposal involves an application to re-establish a licensed healthcare
22 facility or service that was provided at a hospital [with fifty (50) or fewer licensed beds]
23 and which was voluntarily discontinued by the applicant under the following

circumstances:

1. The termination or voluntary closure of the hospital:

a. Was not the result of an order or directive by the cabinet, governmental agency, judicial body, or other regulatory authority;

b. Did not occur during or after an investigation by the cabinet, governmental agency, or other regulatory authority;

c. Did occur while the facility was in substantial compliance with applicable administrative regulations and was otherwise eligible for re-licensure; and

d. Was not an express condition of any subsequent Certificate of Need approval;

2. The application to re-establish the healthcare facility or service that was voluntarily discontinued is filed no more than one (1) year from the date the hospital last provided the service which the applicant is seeking to re-establish;

3. A proposed healthcare facility shall be located within the same county as the former healthcare facility and at a single location; and

4. The application shall not seek to re-establish any type of bed utilized in the care and treatment of patients for more than twenty-three (23) consecutive hours; or

~~(f)~~~~(4)~~ 1. The proposal involves an application to establish an ambulatory surgical center which does not charge its patients and does not seek or accept commercial insurance, Medicare, Medicaid, or other financial support from the federal government; and

2. The proposed ambulatory surgical center shall utilize the surgical facilities of an existing licensed ambulatory surgical center during times the host ambulatory surgical center is not in operation.

1 (3) A Certificate of Need approved for an application submitted under subsection
2 (2)(f)(4) of this section shall state the limitations specified under subsection (2)(f)(4)1.
3 and 2. of this section.

4 (4) If an application is denied nonsubstantive review status by the Office of Health
5 Policy, the application shall automatically be placed in the formal review process.

6 (5) If an application is granted nonsubstantive review status by the Office of Health
7 Policy, notice of the decision to grant nonsubstantive review status shall be given to the
8 applicant and all known affected persons.

9 (6)(a) If an application is granted nonsubstantive review status by the Office of
10 Health Policy, any affected person who believes that the applicant is not entitled to
11 nonsubstantive review status or who believes that the application should not be
12 approved may request a hearing by filing a request for a hearing within ten (10) days of
13 the notice of the decision to conduct nonsubstantive review.

14 (b) The provisions of 900 KAR 6:090 shall govern the conduct of all nonsubstantive
15 review hearings.

16 (c) Nonsubstantive review applications shall not be comparatively reviewed unless
17 the capital expenditure proposed involves the establishment or expansion of a health
18 facility or health service for which there is a component in the State Health Plan.

19 (d) Nonsubstantive review applications [but] may be consolidated for hearing
20 purposes.

21 (7) If an application for certificate of need is granted nonsubstantive review status by
22 the Office of Health Policy, there shall be a presumption that the facility or service is
23 needed and a presumption that the facility or service is consistent with the State Health

1 ~~Plan[and an application granted nonsubstantive review status by the Office of Health~~
2 ~~Policy shall not be reviewed for consistency with the State Health Plan].~~

3 (8) Unless a hearing is requested pursuant to 900 KAR 6:090, the Office of Health
4 Policy shall approve each application for a certificate of need that has been granted
5 nonsubstantive review status [if:

6 ~~—(a) The application does not propose a capital expenditure; or~~

7 ~~—(b) The application does propose a capital expenditure, and the Office of Health~~

8 ~~Policy finds the facility or service with respect to which the capital expenditure proposed~~
9 ~~is needed, unless the cabinet finds that the presumption of need provided for in~~
10 ~~subsection (7) of this section has been rebutted by clear and convincing evidence by an~~
11 ~~affected party].~~

12 (9) The cabinet shall disapprove an application for a certificate of need that has
13 been granted nonsubstantive review if the cabinet finds that the:

14 (a) Applicant is not entitled to nonsubstantive review status; or

15 (b) Presumption of need or presumption that the facility or service is consistent with
16 the State Health Plan provided for in subsection (7) of this section has been rebutted by
17 clear and convincing evidence by an affected party.

18 (10) In determining whether an application is consistent with the State Health Plan,
19 the cabinet, in making a final decision on an application, shall apply the latest criteria,
20 inventories, and need analysis figures maintained by the cabinet and the version of the
21 State Health Plan in effect at the time of the public notice of the application.

22 (11) In determining whether an application is consistent with the State Health Plan
23 following a reconsideration hearing pursuant to KRS 216B.090 or a reconsideration

1 hearing which is held by virtue of a court ruling, the cabinet shall apply the latest criteria,
2 inventories, and need analysis figures maintained by the cabinet and the version of the
3 State Health Plan in effect at the time of the reconsideration decision or decision
4 following a court ruling.

5 (12) A decision to approve or disapprove an application which has been granted
6 nonsubstantive review status shall be rendered within thirty-five (35) days of the date
7 that nonsubstantive review status has been granted.

8 (13)[(14)] If a certificate of need is disapproved following nonsubstantive review, the
9 applicant may:


10 (a) Request that the cabinet reconsider its decision pursuant to KRS 216B.090 and
11 900 KAR 6:065;

12 (b) Request that the application be placed in the next cycle of the formal review
13 process; or

14 (c) Seek judicial review pursuant to KRS 216B.115. (36 Ky.R. 239; Am. 626; 808;
15 eff. 10-28-2009; 38 Ky.R. 339; 1007; 1140; eff. 12-7-2011; 39 Ky.R. 857; 1467; 1695;
16 eff. 3-8-2013.)

900 KAR 6:075

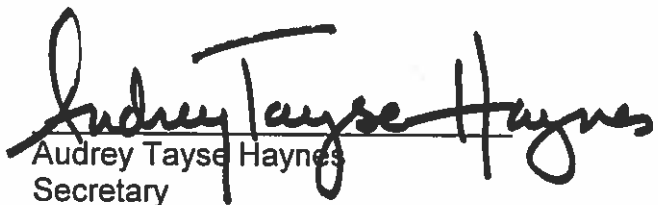
REVIEWED:



Emily Whelan Parento
Executive Director
Office of Health Policy

4/16/14
Date

APPROVED:



Audrey Tayse Haynes
Secretary
Cabinet for Health and Family Services

5/7/14
Date

900 KAR 6:075

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on June 23, 2014, at 9:00 a.m. in Conference Suite B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by June 16, 2014, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until June 30, 2014. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40621, Phone: 502-564-7905, Fax: 502-564-7573, email: tricia.orme@ky.gov

REGULATORY IMPACT ANALYSIS AND TEIRING STATEMENT

Administrative Regulation Number: 900 KAR 6:075

Contact Person: Diona Mullins, (502) 564-9592

1. Provide a brief summary of:
 - (a) What this administrative regulation does: This administrative regulation establishes the guidelines for review of certificate of need applications which are granted nonsubstantive review.
 - (b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with the content of the authorizing statutes, specifically KRS 216B.040(2)(a)1 and KRS 216B.095.
 - (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing the requirements necessary for consideration of nonsubstantive review of certificate of need applications.
 - (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 216B.095 allows a certificate of need applicant to waive a formal review process and request nonsubstantive review if specific conditions are met. This regulation establishes the requirements necessary for consideration of nonsubstantive review of certificate of need applications.
2. If this is an amendment to an existing administrative regulation, provide a brief summary of:
 - (a) How the amendment will change this existing administrative regulation: The regulation is being revised to be consistent with KRS 216B.095(4) to require the Cabinet to consider consistency with the State Health Plan when reviewing a nonsubstantive certificate of need application. Also, the amendment will delete select proposal scenarios from the listing of proposals that may be granted nonsubstantive review status.
 - (b) The necessity of the amendment to this administrative regulation: The amendment is necessary to be consistent with KRS 216B.095(4) which requires the Cabinet to consider consistency with the State Health Plan when reviewing a nonsubstantive certificate of need application..
 - (c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation establishes requirements necessary for consideration for nonsubstantive review of certificate of need applications.
 - (d) How the amendment will assist in the effective administration of the statutes: This administrative regulation establishes requirements necessary for consideration for nonsubstantive review of certificate of

need applications.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects an entity wishing to file a nonsubstantive review certificate of need application. Annually, approximately 150 certificate of need applications are filed.
4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
 - (a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: A certificate of need application requesting nonsubstantive review will be required to meet the requirements of this regulation, including the amendment to require a nonsubstantive review application to address consistency with the State Health Plan if the Plan addresses the proposed service.
 - (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to entities to comply with this amendment.
 - (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The amendment is necessary to be consistent with KRS 216B.095(4) which requires the Cabinet to consider consistency with the State Health Plan when reviewing a nonsubstantive certificate of need application..
5. Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: No cost
 - (b) On a continuing basis: No cost
6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: No funding is necessary since there is no cost to implementing this administrative regulation.
7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary.
8. State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees and does not increase any fees either directly or indirectly.
9. TIERING: Is tiering applied? (Explain why or why not)
Tiering was not appropriate in this administrative regulation because the

administrative regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 900 KAR 6:075

Contact Person: Diona Mullins

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Health care facilities owned by the state, county, or city which submit certificate of need applications requesting nonsubstantive review will be impacted by this regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.040(2)(a)1 and KRS 216B.095.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment will not generate additional revenue for state or local government during the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment will not generate additional revenue for state or local government during subsequent years.

(c) How much will it cost to administer this program for the first year? No additional costs are necessary to administer this program during the first year.

(d) How much will it cost to administer this program for subsequent years? No additional costs are necessary to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation